OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Impact of the Select Agent Regulations

ACTION: Request for Public Comment.

SUMMARY: Public comment is requested on the impact that the Select Agent Regulations have had on science, technology, and national security, and on the benefits, costs, and limitations of these regulations. Drawing on these comments and other information available to it, a Fast Track Action Committee under the Committee on Homeland and National Security of the National Science and Technology Council will review the impacts and consider options to address the identified challenges or gaps concerning those regulations. Comments of up to three pages or fewer (12,000 characters) are requested and must be received by 5:00 pm ET on March 30, 2015 to be considered.

DATES: Comments must be received by 5:00 pm ET on March 30, 2015 to be considered.

ADDRESSES: You may submit comments by any of the following methods:

- E-mail: SAReview@hq.dhs.gov. Include "SAR Comments" in the subject line of the message.
- Mail: Attn: Gerald L. Epstein, Ph.D., Co-Chair, Fast Track Action Committee, Deputy Assistant Secretary for Chemical, Biological, Radiological, and Nuclear Policy, U.S. Department of Homeland Security, 245 Murray Lane SW, Mail Stop #0315, Washington, DC 20528. Please allow sufficient time for security processing of postal mail.

Instructions: Response to this request for public comment is voluntary. Responses exceeding 12,000 characters or three pages will not be considered. Submission via email is preferred. Responses to this request for public comment may be posted online. The Office of Science and Technology Policy (OSTP) therefore requests that no business proprietary information, copyrighted information, or sensitive personally identifiable information be submitted in response to this request. Please note that the U.S. Government will not pay for response preparation, or for the use of any information contained in the response.

FOR FURTHER INFORMATION CONTACT:

Gerald Epstein, Co-Chair, Fast Track Action Committee, at SAReview@hq.dhs.gov, (202)-282-9078.

SUPPLEMENTARY INFORMATION:

This request for public comment offers the opportunity for interested individuals and organizations to comment on the impact that the Select Agent Regulations (SAR) have had on science, technology, and national security, and on the benefits, costs, and limitations of these regulations. The SAR (7 CFR part 331,9 CFR part 121, and 42 CFR part 73, http://www.selectagents.gov/regulations.html) address the possession, use, and transfer of biological select agents and toxins – those agents and toxins that have been determined by the Secretary of Health and Human Services (HHS) or the Secretary of Agriculture as having the potential to pose a severe threat to public, animal or plant health or to animal or plant products. It is important that biological select agents and toxins are regulated in a way that effectively allows for research and development to enhance science, health, and national security.

White House Memorandum for Enhancing Biosafety and Biosecurity

Broad stakeholder engagement with respect to the impact of the SAR is one of the items called for in an August 18, 2014, White House memo on *Enhancing Biosafety and Biosecurity in the United States*, which outlined a series of immediate and longer-term steps the government would take to address the underlying causes of a series of biosafety incidents at U.S. government laboratories earlier that year. Though most of the actions were directed at federally funded laboratories, the Memo recognized that many stakeholders (e.g., regulators, regulated, or other parties interested in the SAR) could provide a broader, deeper understanding of the impact of the SAR.

Questions Regarding the Select Agent and Toxin Regulations

We invite comments on any aspect of the SAR. Comments are sought that identify concrete impacts and/or propose recommendations to ameliorate or resolve identified challenges or gaps. We welcome comments that separately address the implementation of the SAR (including the costs, benefits and impacts of implementation), the regulations themselves, and any broader issues pertaining to the safety and security of potentially dangerous biological microorganisms and toxins.

While all comments are welcome, the following questions may help you frame your response:

1. What are the specific benefits, challenges, and impacts in implementing the SAR with respect to: (1) scientific research (e.g., quality, breadth, international competitiveness, or other outcomes or consequences)?; (2) safety and security (e.g., biocontainment,

biosafety, physical security, cybersecurity, and personnel suitability)?; and, 3. public or agricultural health and response (e.g. ability to respond rapidly and effectively to incidents and the development/availability of medical countermeasures)?

2. What gaps exist in the SAR (e.g., reporting, aggregated data collection, ability to transfer material across international borders) and what specific recommendations would fill those gaps?
3. Are facilities that possess, use, or transfer biological select agents and toxins in the U.S. safer than they were before the SAR went into effect in close to its current form in 2003? If so, to what extent are the SAR responsible?
4. The SAR strike a balance between avoiding harm (e.g., preventing safety or security lapses) and seeking benefits (e.g., conducting research and public or agricultural health activities). Do you think that balance has been struck appropriately? If not, what specific aspects of the SAR should be emphasized more, and what should be emphasized less?
5. Have the regulations unduly impaired research and other applications of select agents and toxins? If so, how? Please provide examples as appropriate, with specific sections of the SAR if possible.
6. If the SAR have unduly impaired research, how can the research and other applications be further promoted, while still protecting against misuse and accidental release? Please provide examples as appropriate, with specific aspects of the SAR if possible.
7. Have the regulations sufficiently protected public and agricultural health and safety against the misuse and accidental release of these agents? If so, or if not, how? Please provide examples as appropriate, with specific sections of the SAR if possible.

8. If the SAR are not sufficient for health and safety protection, how can health and safety be better protected while still facilitating legitimate use of select agents and toxins? Please provide recommended changes to the specific sections of the SAR if appropriate.

9. Describe how the overall costs of the SAR are or are not appropriately balanced with their overall benefits.

10. The SAR regulate the use, transfer, or possession of a specific list of potentially dangerous pathogens and toxins. Is designing the regulations around a list of agents advantageous or disadvantageous? If disadvantageous, in what other way can the regulations be organized and implemented?

11. Research today is a thoroughly international activity, with scientists and research materials constantly crossing national borders. Security threats today likewise extend across national borders. Are the SAR appropriately configured to accommodate these international issues? If not, how could they be improved?

12. Are the SAR appropriately configured to accommodate changes in science and technology such as, but not limited to, advances in synthetic biology, genetic engineering, or viral systematics? If not, how can they be reconfigured to better do so? What scientific and technical advances might improve the function or lessen the costs and burdens of the SAR?

Ted Wackler, Deputy Chief of Staff and Assistant Director

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